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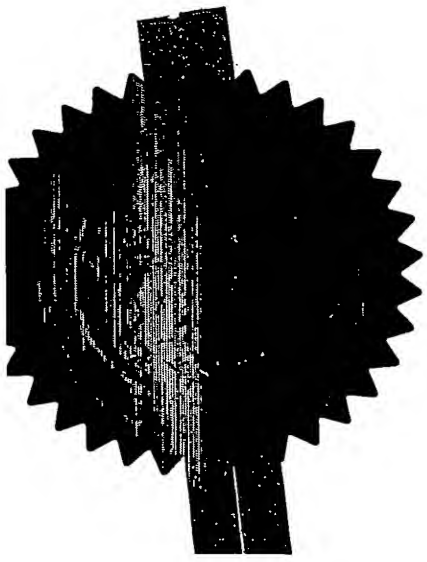

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22JUL03 E824131-1 D00027
P01/7700 0.00-0317003.2

1.	Your reference	38.80932
2.	Patent application number *(The Patent Office will fill in this part)*	0317003.2
3.	Full name, address and postcode of the or of each applicant *(underline all surnames)*	Imperial College Innovations Limited 47 Prince's Gate Exhibition Road London SW7 2QA
	Patents ADP number *(if you know it)*	07409436003
	If the applicant is a corporate body, give country/state of incorporation	England
4.	Title of the invention	Stent
5.	Name of your agent *(if you have one)*	Frank B. Dehn & Co.
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	179 Queen Victoria Street London EC4V 4EL
	Patents ADP number *(if you know it)*	166001 ✓

6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7.	If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing *(day / month / year)*

8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:* *a) any applicant named in part 3 is not an inventor, or* *b) there is an inventor who is not named as an applicant, or* *c) any named applicant is a corporate body.* *See note (d))*	Yes

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Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
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Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

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A.J. Piésold
020 7206 0600

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80932.621

Stent

This invention relates to stents for insertion in a fluid conduit of the human or animal body.

Stents are generally tubular devices used for providing physical support to blood vessels, i.e. they can be used to help prevent kinking or occlusion of blood vessels such as veins or arteries and to prevent their collapse after dilatation or other treatment.

Stents can be broadly divided into two main categories: balloon expandable stents and self-expanding stents. In the case of the former the material of the stent is plastically deformed through the inflation of a balloon, so that after the balloon is deflated the stent remains in the expanded shape. Such stents are manufactured in the "collapsed" condition, ready for delivery, and may be expanded to the expanded condition when inside the vessel or other fluid conduit.

Self-expanding stents are also designed to be delivered in the collapsed condition and when released from a constraining delivery system the stent expands to its expanded condition of a predetermined size. This effect is achieved by using the elasticity of the material and/or a shape-memory effect. In the case of shape-memory stents a commonly used material is nitinol.

Many different designs of stents are available on the market. They are made from a variety of materials providing corrosion resistance and biocompatibility. They are made from sheet, round or flat wire or tubing. They are generally cylindrical but also longitudinally flexible so as to conform to the curvature of the fluid conduit into which they are inserted.

It has been proposed in EP 1042997 to provide stents the flexibility of which varies along their length, in order to facilitate placement of one end of the stent in a narrower or tortuous coronary artery, or

to achieve stenting of a bend of a particular coronary artery. This proposal involves providing the stent with a pattern of interconnected struts, with the strut thickness being variable along the length of the stent.

We have previously proposed that the flow pattern in arteries including the swirling pattern induced by their non-planar geometry operates to inhibit the development of vascular diseases such as thrombosis, atherosclerosis and intimal hyperplasia.

In WO 98/53764, there is disclosed a stent for supporting part of a blood vessel. The stent includes a supporting portion around which or within which part of a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part. The supporting portion of the stent is shaped so that flow between graft and host vessel is caused to follow a non-planar curve. This generates a swirl flow, to provide a favourable blood flow velocity pattern which reduces the occurrence of vascular disease, particularly intimal hyperplasia.

In WO 00/32241, there is disclosed another type of stent, in this case including a supporting portion around which or within which part of an intact blood vessel other than a graft can be placed. This supporting portion can prevent failure of the vessel through blockage, kinking or collapse. Again, the supporting portion of the stent is of a shape and/or orientation whereby flow within the vessel is caused to follow a non-planar curve. Favourable blood flow velocity patterns can be achieved through generation therein of swirl flow within and beyond the stent. Failures in blood vessels through diseases such as thrombosis, atherosclerosis, intimal hyperplasia can thereby be significantly reduced.

Further aspects of how swirl flow is beneficial are explained in the above publications. It is further explained in Caro et al. (1998) J. Physiol. 513P,2P how

non-planar geometry of tubing inhibits flow instability.

It has been proposed in WO 00/38591 to provide a stent with internal helical grooving or ridging to induce helical flow. Figures 9 to 12 of this document show a stent in the form of a mesh cylinder, with vane members attached to the inside of the cylinder so as to project into the fluid passage and guide the flow. However the presence of vanes projecting into the flow may obstruct the flow and increase flow resistance, especially if there is any build-up of material on the vanes. Also, the use of vanes in an otherwise cylindrical tube may not reliably induce swirl flow across the entire cross-section of flow. There may be a tendency for the flow nearer to the centre of the tube to follow a linear path, particularly for flows at higher Reynolds numbers. Further, the provision of vanes over a relatively short length of flow is likely to create only a temporary alteration of flow characteristics, with the flow reverting to a normal pattern at a distance downstream of the vanes.

In WO 02/098325 there are various proposals for cylindrical external structures for placement outside of blood flow conduits in order to influence the internal geometry of the conduit lumen. By providing ribs or other radially inwardly projecting helical members, the cross-sectional shape of the lumen is modified from the outside of the conduit. The various structures are not for use as stents capable of delivery internally of a conduit in a collapsed condition and for expansion at the target site.

In WO 00/32241 internal stents for establishing and/or maintaining non-planar curvature of a blood vessel are shown. Figure 5 of this document shows a clip which is part coiled or at least part helical of shape memory alloy, affixed to a cylindrical wire mesh. With such an arrangement, when the clip moves to a more coiled condition once the stent has been installed, it

will cause the cylindrical wire mesh to adopt a non-planar curvature but it will also cause it to twist. Since it is undesirable for the stent to apply torsional loading to the inside wall of the blood vessel, this twisting effect may limit the number of helical turns imposed by the clip, for example to one or less than one turn. However, the objective of inducing or maintaining swirl flow in the vessel is assisted by increasing the number of helical turns.

We have now found a way of producing an internal stent capable of moving from a collapsed condition to an expanded condition without significant twisting but which facilitates flow within the stent supported fluid conduit to follow a non-planar curve, i.e. to swirl.

According to a first aspect of the invention there is provided a stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition, the stent comprising an outer wall for engagement with the conduit, the outer wall having a helical portion which in the expanded condition extends longitudinally and circumferentially, and which, upon expansion of the stent from the collapsed condition to the expanded condition resists, extension.

Flow within the fluid conduit supported by such a stent can follow a non-planar curve, promoting swirl flow, the benefits of which are discussed above.

Preferably, the centre line of the stent in the expanded condition follows a substantially helical path. In other words, the centroids of adjacent cross-sectional slices through the stent define a helical locus or centre line. This may be achieved by a non-rotationally symmetric shape (rotational symmetry of order one) when in the expanded condition, which "twists" along the length of the stent. It may however also be achieved if the stent has a circular or other rotationally symmetrical cross-sectional shape,

providing the cross-section as a whole shifts laterally from one "slice" to the next. It is generally preferred to avoid any pronounced grooves or ridges as these may have the opposite of the desired effect of improving flow characteristics, i.e. they may obstruct the flow, facilitate deposit build up or create stagnant regions.

The amplitude and pitch of the helical centre line may be chosen to vary along the length of the stent, if desired. Variation of amplitude can be achieved by increasing or decreasing the resistance to extension provided by the helical portion, whilst variation in pitch may be achieved by varying the pitch of the helical portion itself. Such variations may for example be desired if it is wished to introduce a gentle swirl at the upstream end of the stent and to increase the swirl effect in the downstream direction.

The stents of the preferred embodiments have a helical portion which has a greater resistance to extension than portions of the stent adjacent to the helical portion. Preferably, the helical portion comprises an increased amount of stent forming material relative to the amount of stent forming material in portions of the stent adjacent to the helical portion. The increased amount of material can provide the required resistance to extension when the stent expands to the expanded condition. The increase may be provided for example by thicker structural members, in the radial direction and/or longitudinal direction and/or circumferential direction. The increased amount may alternatively or additionally be provided by the use of extra stent forming members. For example, in the case of a woven stent, the helical portion may be provided by weaving in one or more extra wires. In other cases, extra struts may be provided.

The helical portion may comprise structural members having bent portions which resist unbending during expansion of the stent. Many stents consist of

structural members bent between nodes or at nodes. In general, when the stent expands some or all of the bent portions unbend as the diameter of the stent increases. The desired resistance to extension may therefore be achieved by the helical portion having structural members with bent portions which resist unbending more than bent portions adjacent to the helical portion.

The helical portion may be arranged to resist extension in the circumferential direction, or to resist extension in the longitudinal direction, or to resist extension in the circumferential and the longitudinal directions. The choice of the appropriate form of the helical portion will generally depend on the type of stent and the manner in which it expands.

The helical portion may be viewed as a helical stripe extending longitudinally and circumferentially of the stent. The stripe may be substantially continuous, as for example in the case of one or more extra wires woven into the stent, or it may be discontinuous, as will be the case where the stent has thicker or otherwise modified structural members which are separated by spaces.

The stent may be of the self-expanding type or it may be balloon expandable. In the case of self-expanding stents, during expansion from the collapsed condition to the expanded condition, the portions which are not part of the helical portion will be seeking to expand due to their elasticity or shape-memory properties. The expansion is resisted in the vicinity of the helical portion by being less expansible. The helical portion may itself extend to some degree during expansion of the stent, and indeed may itself be seeking to expand due to its elasticity or shape-memory properties. However, the rest of the stent will be seeking to expand more than the helical portion so that in effect the helical portion provides a resistance to extension. This will enable the stent to assume the

desired shape for promoting swirl flow in a fluid conduit supported by the stent.

In the case of a balloon expandable stent, the force to expand the stent is supplied by the balloon and the helical portion will allow less expansion, which will normally mean a lesser degree of plastic deformation, than the rest of the stent.

The basic geometry of the stent may be of the many available types, such as coil stents, helical spiral stents, woven stents, sequential ring stents, closed cell sequential ring stents, and open cell stents. They may be made by coiling, braiding or knitting wires, by laser cutting from tubing, by electric discharge milling (EDM), by chemical etching or by other known methods. They may be made from a variety of materials, including stainless steel, nitinol, tantalum, platinum iridium, niobium alloy, cobalt alloy or polymers (such as biodegradable polymers).

According to a second aspect of the invention there is provided a balloon expandable stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition, the stent comprising a balloon having an expandable wall, the wall having a helical portion which in the expanded condition extends longitudinally and circumferentially, and which, upon expansion of the balloon from the collapsed condition to the expanded condition, resists extension.

In some circumstances the main stent body, i.e. that which is left in the fluid conduit after the balloon is removed, may be of a conventional type before expansion. After expansion, however, it retains (by plastic deformation) a shape which corresponds to that determined by the balloon with the helical portion of reduced extensibility.

Alternatively, the stent may have an outer wall for engagement with the fluid conduit in accordance with the

first aspect of the invention, i.e. also with a helical portion which resists extension. The helical portions of the balloon and the stent outer wall would then preferably be arranged in registration with each other.

The helical portion of the balloon expandable wall may have a wall thickness greater than that of adjacent wall portions. This could easily be achieved by adding a helical "stripe" around the outside of a balloon of uniform wall thickness, thereby creating the thicker helical portion.

Certain preferred embodiments of the invention will now be described by way of example and with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a first embodiment of stent in accordance with the invention;

Figure 2 is a longitudinal cross-sectional of the stent;

Figure 3 is a transverse cross-sectional view of the stent on the line III-III of Figure 2;

Figure 4 is a longitudinal cross-sectional view of a second embodiment of stent;

Figure 5 is a transverse cross-sectional view of the second embodiment on the line V-V of Figure 4;

Figure 6 is a fragmentary longitudinal cross-sectional view of a third embodiment of stent;

Figure 7 is a fragmentary view of a longitudinal cross-section of a fourth embodiment of stent;

Figure 8 is a view of an experimental balloon; and

Figure 9 is a view of another experimental balloon.

Figures 1 to 3 show a woven stent 2 in the expanded condition. The stent has the usual wire strands 4 arranged in a mesh and collectively forming a mesh like outer wall 7. It is also provided with a helical portion or "stripe" 6 extending longitudinally and circumferentially of the stent. The helical portion 6 in this case consists of two additional strands 8 woven into the main mesh.

The effect of the helical portion 6 is to create a cross-sectional shape approximating to a circle with a segment removed in the region corresponding to the helical portion, as seen in Figure 3. This cross-sectional shape has a centroid 9. The locus of centroids 9 along the length of the stent defines a helical centre line 40, shown in Figure 1. The centre line 40 follows a helical path about a longitudinal axis 30 which is at the centre of an imaginary cylindrical envelope 20 within which the stent is contained. The amplitude A of the helix is shown in Figure 1.

In use, the stent is deployed at a target site and is then expanded by a balloon or by the elasticity or shape-memory properties of the strands 4. The helical portion 6 acts to restrict extension (at least in the longitudinal direction) and hence the expanded stent adopts the configuration described, in which the centre line of the stent follows a helical path. The outer wall 7 engages the fluid conduit wall and influences its shape so that the lumen of the fluid conduit at the target site also tends to have a helical centre line. This will help to promote swirl flow along the lumen. The handedness ("s" or "z") of the stent will normally be chosen to complement the local fluid conduit geometry so as to enhance any swirl flow already existing upstream of the stent and not to cancel it.

In the embodiment shown in Figures 1 to 3 two helically arranged wires 8 are provided, but other numbers of wires could be used. In addition, the wires could be designed to provide the greatest resistance to extension in the middle of the helical portion 6, with less resistance being provided towards the edges of the helical portion, for example by grading the wires with a thickest wire in the middle and thinner wires towards the edges. Such an arrangement could ensure that the shape of the expanded stent, when viewed in transverse cross-section, does not have any sharp ridges or grooves

and ideally corresponds closely to a circle.

In a modified embodiment a helical portion is formed by a single helically arranged wire 8 to produce a stent of substantially circular cross-section. The single wire can provide resistance to longitudinal extension during expansion of the stent and cause it to define a lumen with a helical centre line. A circular cross-sectional shaped stent can still provide the desired swirl inducing effect providing the centre line of the lumen is helical.

Figures 4 and 5 show an embodiment of a stent of the so-called helical spiral type. In this case the basic stent design consists of a wire 10 in a wave form, shown at 12, with that wave form extending in the manner of a coil from one end of the stent to the other. Longitudinally adjacent waves of the wave form 12 are joined by connecting elements 14. In the expanded condition the wavelength of the waves is, for most of the circumference of the stent, a distance D. In the region of the helical portion 6 this wavelength is reduced to less than D. The effect of the reduced wavelength is to cause the lumen of the fluid conduit in which the stent is expanded to adopt the desired configuration for promoting swirl flow in the lumen of the fluid conduit.

In the collapsed condition of the stent of Figures 4 and 5 the wavelength of the waves of the wave form 12 is reduced throughout the stent. During expansion the wavelength in the region of the helical portion 6 increases least. Extension in the circumferential direction is resisted by the helical portion 6. This could for example be achieved providing that the natural shape of the waves in the helical portion 6 is one having a smaller wavelength than D. This may be appropriate for example if the stent is made by being cut out from a metal sheet or tube.

Another way of achieving the reduced

circumferential expansion in the region of the helical portion 6 would be to provide short bridges 16 between circumferentially adjacent portions of the wave in the helical portion 6. Such a bridge 16 is shown in Figure 5. Further bridges would be provided at intervals along the helical portion.

Figure 7 shows a stent of the closed cell type with "v" hinges between adjacent cells. In this case the helical portion 6 is provided by forming a helical line of cells 18 which are smaller than the other cells 20. When the stent is expanded, either by a balloon, or by the elastic or shape-memory properties of the material from which the stent is formed, the cells 20 expand to a predetermined size. The cells 18 expand to a smaller predetermined size and hence resist extension. As with the other stents, the result is that the lumen of the fluid conduit in which the stent is expanded adopts a configuration promoting swirl flow.

The various stents shown and described are provided with a single helical portion 6. However, other numbers of helical portions could be provided. Preferably the stents are non-rotationally symmetrical (rotational symmetry of order 1), as this can ensure that the centre line of the expanded stent follows a helical path.

Figure 8 shows the result of an experiment carried out on a toy balloon 55. The balloon was of the elongated type. It was supported, without being inflated, on a cylindrical rod and a plastic strip 51 cut from another balloon was glued onto the outside of the supported balloon to form a longitudinally and circumferentially extending helical strip 6. A straight line 50 was drawn along the balloon. After the glue had set, the balloon was inflated and the inflated balloon is shown in Figure 8.

It will be seen that the inflated balloon 55 has a helical lumen. As with the stents, it has a helical centre line 40, which follows a helical path about a

longitudinal axis 30. The longitudinal axis is at the centre of an imaginary cylindrical envelope 20 within which the balloon is contained. The amplitude A of the helix is shown in Figure 8.

It will be noted that after inflation the straight line 50 adopts a wave shape which remains consistently along the same side of the balloon, so that the entire line 50 remains visible in the elevation view of Figure 8. This indicates that the balloon has gone from the collapsed condition to the inflated condition without any significant twisting. There is no net twisting along the length of the balloon. A similar effect in an expanding stent in accordance with the preferred embodiments of the invention means that as the stent expands and engages the inside of a fluid conduit in which it is sited it does not impose excessive torsional loads on that conduit. This is beneficial in the case of the conduit being a blood vessel, for example, since torsion is resisted by the external tethering of the blood vessel.

Thus in the preferred embodiments the stents expand from the collapsed condition to the expanded condition without substantial twisting. The lack of twisting of the stent also enables it to have a plurality of turns without causing e.g. a blood vessel to twist during expansion, such twisting being undesirable because of the tethering of the blood vessel.

The balloon of Figure 8 starts as a cylindrical membrane with a helical portion which is of greater (in this case double) wall thickness than the rest of the balloon. During inflation the thicker helical portion will tend to resist extension in all directions, including circumferential and longitudinal directions, thereby influencing the shape of the expanded balloon. Instead of adopting the normal cylindrical shape, the balloon forms a shape with a helical centre line 40.

In another experiment, a plastic strip 52 was made

with a tapered width, rather than with parallel side edges. It was found that the amplitude A of the helical centre line 40 was larger where the width of the strip was wider. This is shown in Figure 9. A thinner strip tends to cause less deviation of the cross-sectional shape of the balloon from a circular shape.

The shape of the expanded experimental balloon membranes may be considered as analogous to that of an expanded stent outer wall or the wall of a balloon used in a balloon expandable stent. Considering therefore the inside of the helical balloon as a lumen or flow path, it will be appreciated that a helical lumen is obtained, giving the desirable flow properties discussed above, without the use of ribs, vanes or other flow guides protruding into the flow.

The experimental results thus show that by introducing a helical portion which resists extension during expansion of a stent, when expanded the stent will adopt a shape causing a fluid conduit which it supports to have a helical lumen, thereby promoting swirl flow. The effect observed in the balloons of Figures 8 and 9 may be obtained in a main stent body, either self-expanding or balloon expandable, and/or in a balloon which is used to expand a balloon expandable stent.

It will be noted that in the preferred embodiments the stent does not rely on the use of thicker wires which themselves provide ribs or flow guides in an otherwise circular cross-section lumen. Rather, the shape of the lumen is modified by the resistance of the helical portion to extension.

Claims

1. A stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition, the stent comprising an outer wall for engagement with the conduit, the outer wall having a helical portion which in the expanded condition extends longitudinally and circumferentially, and which, upon expansion of the stent from the collapsed condition to the expanded condition, resists extension.

2. A stent as claimed in claim 1, wherein the centre line of the stent in the expanded condition follows a substantially helical path.

3. A stent as claimed in claim 1 or 2, wherein the helical portion comprises an increased amount of stent forming material relative to the amount of stent forming material in portions of the stent adjacent to the helical portion.

4. A stent as claimed in claim 1, 2 or 3, wherein the helical portion comprises structural members having bent portions which resist unbending during expansion of the stent.

5. A stent as claimed in any of claims 1 to 4, being a self-expanding stent.

6. A stent as claimed in any of claims 1 to 4, being a balloon expandable stent.

7. A balloon expandable stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition, the stent comprising a balloon having an

expandable wall, the wall having a helical portion which in the expanded condition extends longitudinally and circumferentially, and which, upon expansion of the balloon from the collapsed condition to the expanded condition, resists extension.

8. A stent as claimed in claim 7, wherein the helical portion of the balloon expandable wall has a wall thickness greater than that of adjacent wall portions.

9. A stent substantially as hereinbefore described with reference to Figures 1 to 3 or Figures 4 and 5 or Figure 6 or Figure 7 of the accompanying drawings.

ABSTRACT

Stent

A stent for insertion in a fluid conduit of the human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition, the stent comprising an outer wall for engagement with the conduit, the outer wall having a helical portion which in the expanded condition extends longitudinally and circumferentially, and which, upon expansion of the stent from the collapsed condition to the expanded condition, resists extension.

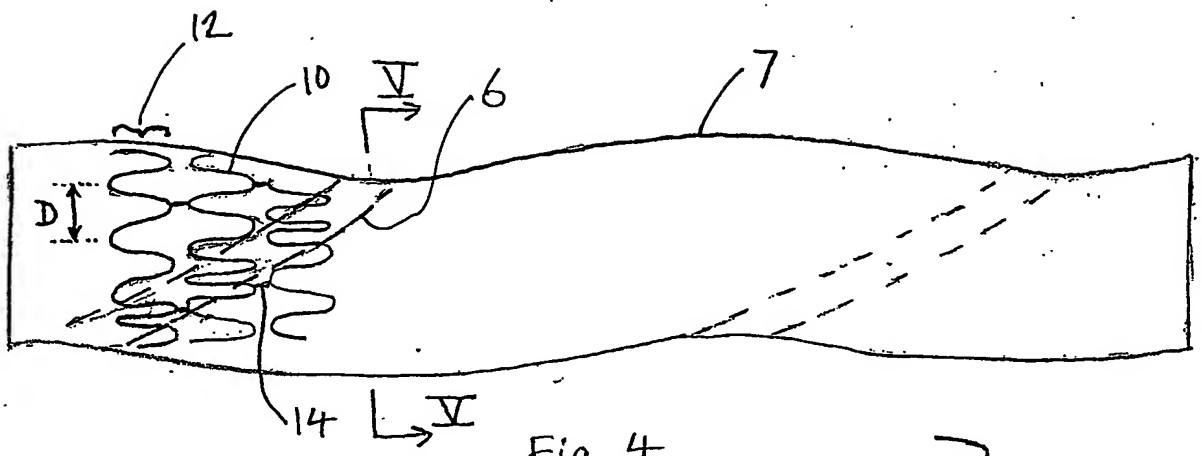

Fig. 4

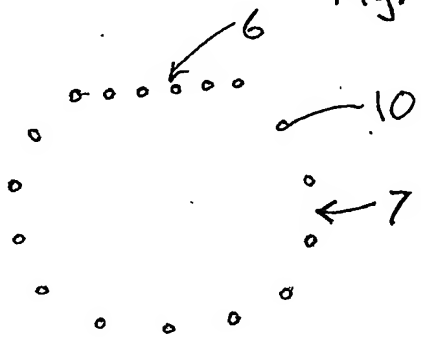

Fig. 5

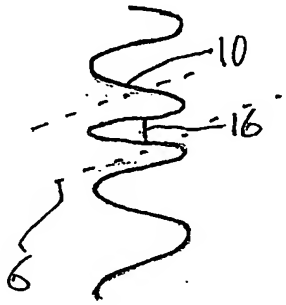

Fig. 6

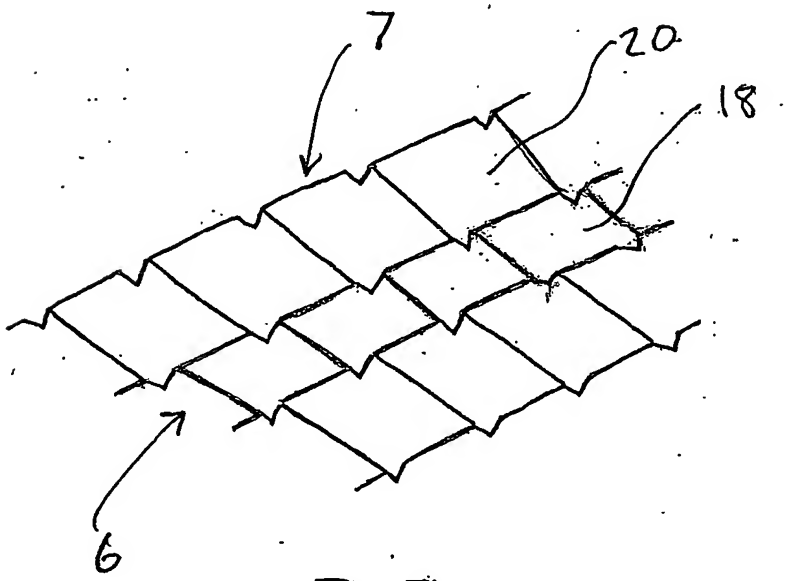

Fig. 7

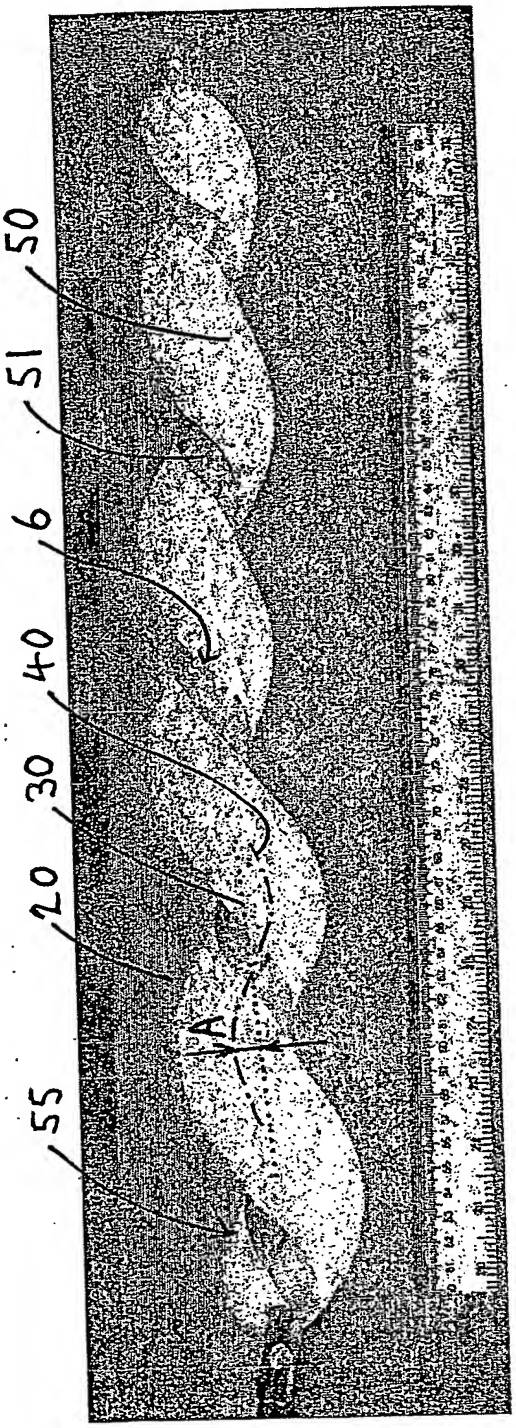

Fig. 8

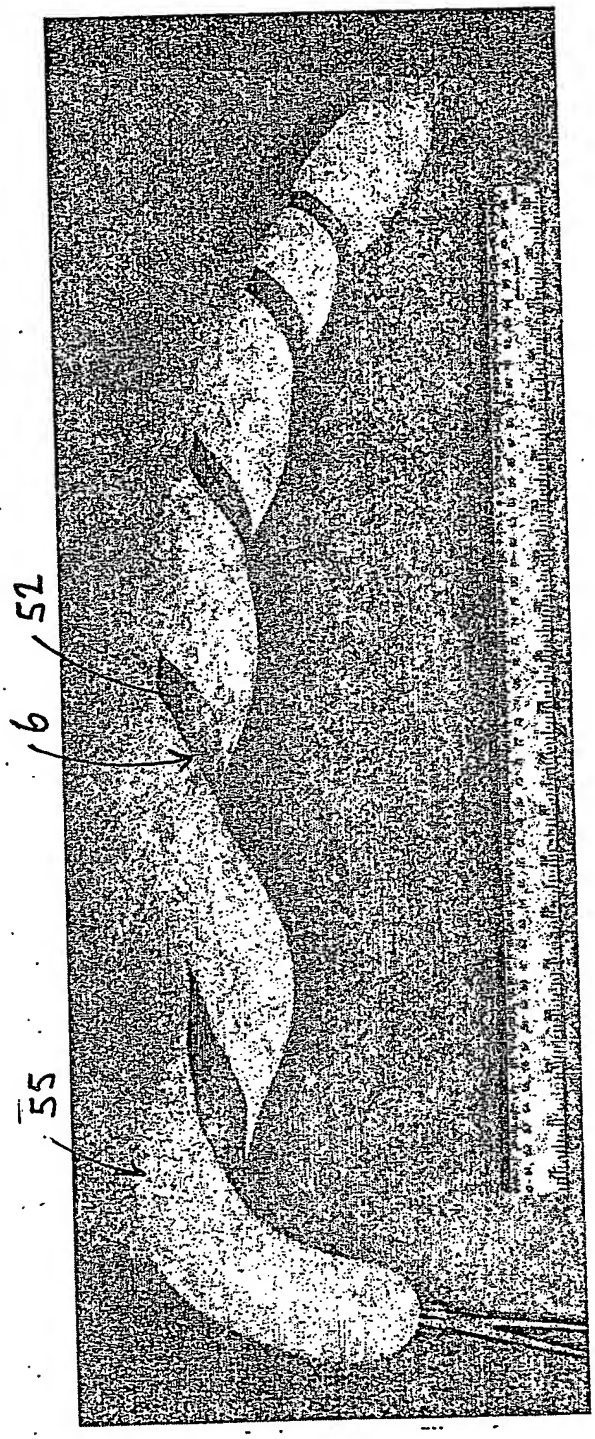

Fig. 9